PTO/SB/64 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)	Docket Number (Optional) 350292003100

First named inventor: Katsuhiro KANO

Application No: 10/593,786 Art Unit: Not Yet Assigned

Filed: March 24, 2005 Examiner: Not Yet Assigned

Title: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR

Attention: Office of PCT Legal Administration
Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee – required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. Petition fee

☐ Small entity – fee $ _____ (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.

☒ Other than small entity – fee $ 1,620.00 (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of Response to Notification of Abandonment (identify type of reply):

☒ has been filed previously on December 4, 2009 .

☒ Response to Notification of Defective Response is also enclosed herewith.

B. The issue fee and publication fee (if applicable) of $ _____ .

☐ has been paid previously on _____ .

☐ is enclosed herewith.

04/08/2010 LLANDGRA 00000028 031952 10593786
01 FC:1453 1620.00 DA

va-298974

3. Terminal disclaimer with disclaimer fee

[X] Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

[ ] A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____ for a small entity or $ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature	April 7, 2010 Date
Jonathan Bockman Typed or printed name	45,640 Registration Number, if applicable
MORRISON & FOERSTER LLP 1650 Tysons Blvd, Suite 400 McLean, Virginia 22102 Address	(703) 760-7769 Telephone Number

Enclosures:

[X] Fee Payment

[X] Reply

[ ] Terminal Disclaimer Form

[ ] Additional sheets containing statements establishing unintentional delay

[X] Other: Copy of the documents filed on December 4, 2009 and copy of Decision

Docket No.: 350292003100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Katsuhiro KANO et al.

Application No.: 10/593,786 Confirmation No.: 4027

Filed: March 24, 2005 Art Unit: Not Yet Assigned

For: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR Examiner: Not Yet Assigned

RESPONSE TO NOTIFICATION OF DEFECTIVE RESPONSE

MS PCT
ATTN: Office of PCT Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notification of Defective Response mailed March 20, 2009, Applicants are concurrently filing the following in addition to the Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b):

1. A copy of the Decision on petition dated February 24, 2010;

2. Statement Under 37 CFR 1.825(a) and 1.825(b);

3. Paper copy of the Sequence Listing;

4. Computer disk containing the Sequence Listing in ASCII format;

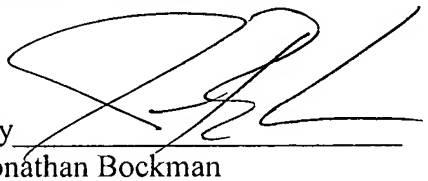
5. Preliminary Amendment.

A copy of the documents submitted on December 4, 2009, in response to the Notification of Abandonment, is also attached for your reference.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **350292003100**.

Dated: April 7, 2010

Respectfully submitted,



By_____

Jonathan Bockman
Registration No.: 45,640
MORRISON & FOERSTER LLP
1650 Tysons Blvd, Suite 400
McLean, Virginia 22102
(703) 760-7769

PTO/SB/17 (10-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2009

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1,620.00

Complete if Known	
Application Number	10/593,786
Filing Date	March 24, 2005
First Named Inventor	Katsuhiro KANO
Examiner Name	Not Yet Assigned
Art Unit	Not Yet Assigned
Attorney Docket No.	350292003100

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 03-1952 Deposit Account Name: Morrison & Foerster LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fees Paid ($)
Utility	330	165	540	270	220	110	
Design	220	110	100	50	140	70	
Plant	220	110	330	165	170	85	
Reissue	330	165	540	270	650	325	
Provisional	220	110	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	52	26
Each independent claim over 3 (including Reissues)	220	110
Multiple dependent claims	390	195

Total Claims _____ - 20 or HP _____ x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of total claims paid for, if greater than 20.

Multiple Dependent Claims: Fee ($) _____ Fee Paid ($) _____

Indep. Claims _____ - 3 or HP = _____ x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets _____ - 100 = _____ Extra Sheets _____ /50 = _____ Number of each additional 50 or fraction thereof (round up to a whole number) x Fee ($) _____ = Fee Paid ($) _____

4. OTHER FEE(S) Fees Paid ($)

Non-English Specification, $130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1453 Petition to revive unintentionally abandoned ... 1,620.00

SUBMITTED BY					
Signature		Registration No. (Attorney/Agent)	45,640	Telephone	(703) 760-7769
Name (Print/Type)	Jonathan Bockman			Date	April 7, 2010

va-298987

24 FEB 2010

United States Patent and Trademark Office

JKB/KKL

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

RECEIVED NV RECORDS

FEB 26 2010

MORRISON & FOERSTER LLP

MORRISON & FOERSTER LLP
1650 TYSONS BOULEVARD
SUITE 400
MCLEAN VA 22102

In re Application of
Kano et al.
Application No.: 10/593,786
PCT No.: PCT/JP2005/006229
Int. Filing Date: 24 March 2005
Priority Date: 24 March 2004
Attorney Docket No.: 350292003100
For: Subtypes Of Humanized Antbody Against Interleuken-6 Receptor

DECISION

This is in response to the petition under 37 CFR 1.181 filed on 04 December 2009.

BACKGROUND

This international application was filed on 24 March 2005, claimed an earlier priority date of 24 March 2004, and designated the U.S. The International Bureau transmitted a copy of the published international application to the USPTO on 29 September 2005. The 30 month time period for paying the basic national fee in the United States expired at midnight on 24 September 2006. Applicants filed *inter alia* the basic national fee on 22 September 2006.

On 27 June 2008, a Notification of Missing Requirements (From PCT/DO/EO/905) was mailed, requiring the submission of additional claims fees, an oath or declaration compliant with 37 CFR 1.497(a) and (b), the surcharge under 37 CFR 1.492(h), an initial computer-readable form (CRF) of the sequence listing, an initial paper or CD copy of the sequence listing, an amendment directing its entry into the specification, and a statement that the content of the CRF is identical to the written sequence listing and, where applicable, contains no new matter.

On 26 August 2008, applicants filed a response.

On 20 March 2009, a Notification of Defective Response (Form PCT/DO/EO/916) was mailed, requiring the submission of a substitute CRF and statement that the content of the CRF is identical to the written sequence listing and, where applicable, contains no new matter.

On 20 April 2009, applicants filed a response.

On 05 October 2009, a Notification of Abandonment (Form PCT/DO/EO/909) was mailed to counsel, indicating that this international application had become abandoned with respect to the national stage in the United States for failure to timely reply to the Notification of Missing Requirements mailed on 27 June 2008.

DISCUSSION

DOCKETED Request for Reconsideration Due
REMINDER: 3/12/10
FINAL DUE DATE: 4/24/10

RECEIVED
FEB 26 2010
MORRISON & FOERSTER LLP

Counsel requests withdrawal of the holding of abandonment, noting that responses were filed on 26 August 2008 and 20 April 2009, and that "a notice indicating that our computer readable form (CRF) was defective was never mailed to us."

Review of the record reveals that the Notification of Missing Requirements mailed on 27 June 2008 required *inter alia* the submission of a CRF, within a period for response that ended as of midnight on 27 January 2009 (if maximally extended under 37 CFR 1.136(a)). On 26 August 2008, applicants filed a CRF, which was evaluated and found to be defective. Applicants were given an additional opportunity to file an acceptable CRF by the Notification of Defective Response mailed on 20 March 2009, which did not re-start the period for response. Instead, it set a one-month time limit to comply (since the extendable period for response to the Notification of Missing Requirements had already expired). Applicants filed a further CRF on 20 April 2009, the last day within said time limit, but this CRF was found to be defective. Therefore, this international application became abandoned for failure to timely reply to the Notification and Missing Requirements and the Notification of Defective Response. By policy, applicants were not entitled to a further opportunity to perfect their response, and the absence of "a notice indicating that our computer readable form (CRF) was defective" prior to the holding of abandonment does not constitute error on the part of the USPTO. Accordingly, it would not be appropriate to withdraw the holding of abandonment on the basis of the present record. Applicants may wish to consider seeking relief under 37 CFR 1.137(b).

DECISION

The petition is **DISMISSED**, without prejudice.

If reconsideration on the merits of this matter is desired, a proper response must be filed within **TWO (2) MONTHS** from the mail date of this decision. Extensions of time may be obtained under 37 CFR 1.136(a).

Any further correspondence with respect to this matter may be filed electronically via EFS-Web selecting the document description "Petition for review and processing by the PCT Legal Office" or by mail addressed to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

/George Dombroske/
George Dombroske
PCT Legal Examiner
Office of PCT Legal Administration
Tel: (571) 272-3283

Docket No.: 350292003100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Katsuhiro KANO et al.

Application No.: 10/593,786 Confirmation No.: 4027

Filed: March 24, 2005 Art Unit: Not Yet Assigned

For: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR Examiner: Not Yet Assigned

STATEMENT UNDER 37 C.F.R. 1.825(a) and 1.825(b)

MS PCT
ATTN: Office of PCT Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned hereby states that the content of the attached paper copy of the substitute Sequence Listing and the computer readable copy of the substitute Sequence Listing submitted in accordance with 37 C.F.R. §§ 1.821-1.825, are identical. The submission of the substitute Sequence Listing does not include new matter.

The substitute Sequence Listing enclosed herewith has been amended to facilitate its administrative processing, and not for reasons related to patentability.

Applicants request consideration and entry of the Sequence Listing paper copy and computer readable copy. Pursuant to 37 C.F.R. 1.77, please enter the paper copy of the Sequence Listing after the Abstract.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and

authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **350292003100**.

Dated: April 7, 2010

Respectfully submitted,

By _____
Jonathan Bockman
Registration No.: 45,640
MORRISON & FOERSTER LLP
1650 Tysons Blvd, Suite 400
McLean, Virginia 22102
(703) 760-7769

SEQUENCE LISTING

<110> KANO, Katsuhiro
TERASHIMA, Isamu

<120> SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKIN-6 RECEPTOR

<130> 35029-20031.00

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His Ala Trp Ser Trp Val Arg Gln Pro Pro Gly Arg Gly Leu Glu Trp
        35                  40                  45
Ile Gly Tyr Ile Ser Tyr Ser Gly Ile Thr Thr Tyr Asn Pro Ser Leu
    50                  55                  60
Lys Ser Arg Val Thr Met Leu Arg Asp Thr Ser Lys Asn Gln Phe Ser
65                  70                  75                  80
Leu Arg Leu Ser Ser Val Thr Ala Ala Asp Thr Ala Val Tyr Tyr Cys
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Ala Arg Ser Leu Ala Arg Thr Thr Ala Met Asp Tyr Trp Gly Gln Gly
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Ser Leu Val Thr Val Ser Ser Ala Ser Thr Lys Gly Pro Ser Val Phe
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Pro Leu Ala Pro Ser Ser Lys Ser Thr Ser Gly Gly Thr Ala Ala Leu
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Thr His Thr Cys Pro Pro Cys Pro Ala Pro Glu Leu Leu Gly Gly Pro
225                 230                 235                 240
Ser Val Phe Leu Phe Pro Pro Lys Pro Lys Asp Thr Leu Met Ile Ser
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Arg Thr Pro Glu Val Thr Cys Val Val Val Asp Val Ser His Glu Asp
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Pro Glu Val Lys Phe Asn Trp Tyr Val Asp Gly Val Glu Val His Asn
        275                 280                 285
Ala Lys Thr Lys Pro Arg Glu Glu Gln Tyr Asn Ser Thr Tyr Arg Val
    290                 295                 300
Val Ser Val Leu Thr Val Leu His Gln Asp Trp Leu Asn Gly Lys Glu
305                 310                 315                 320
Tyr Lys Cys Lys Val Ser Asn Lys Ala Leu Pro Ala Pro Ile Glu Lys
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Thr Ile Ser Lys Ala Lys Gly Gln Pro Arg Glu Pro Gln Val Tyr Thr
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Leu Pro Pro Ser Arg Asp Glu Leu Thr Lys Asn Gln Val Ser Leu Thr
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Cys Leu Val Lys Gly Phe Tyr Pro Ser Asp Ile Ala Val Glu Trp Glu
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            20                  25                  30
Leu Asn Trp Tyr Gln Gln Lys Pro Gly Lys Ala Pro Lys Leu Leu Ile
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Tyr Tyr Thr Ser Arg Leu His Ser Gly Val Pro Ser Arg Phe Ser Gly
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65                  70                  75                  80
Glu Asp Ile Ala Thr Tyr Tyr Cys Gln Gln Gly Asn Thr Leu Pro Tyr
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Thr Ala Ser Val Val Cys Leu Leu Asn Asn Phe Tyr Pro Arg Glu Ala
    130                 135                 140
Lys Val Gln Trp Lys Val Asp Asn Ala Leu Gln Ser Gly Asn Ser Gln
145                 150                 155                 160
Glu Ser Val Thr Glu Gln Asp Ser Lys Asp Ser Thr Tyr Ser Leu Ser
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Ser Thr Leu Thr Leu Ser Lys Ala Asp Tyr Glu Lys His Lys Val Tyr
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1 5

Docket No.: 350292003100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Katsuhiro KANO et al.

Application No.: 10/593,786 Confirmation No.: 4027

Filed: March 24, 2005 Art Unit: Not Yet Assigned

For: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR Examiner: Not Yet Assigned

FIRST PRELIMINARY AMENDMENT

MS PCT
ATTN: Office of PCT Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to examination on the merits, Applicants respectfully request entry on this Preliminary Amendment for the above-captioned patent application.

Amendments to the Specification begin on page 8.

Remarks begin on page 9.

AMENDMENTS

In the Specification:

Page 4, please replace the paragraph starting on line 13, with the following amended paragraph:

Fig. 1 shows the result of liquid chromatography in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3), in which the top graph is a chromatogram detected by a UV at 215 nm and the bottom graph is a base peak chromatogram.

Page 4, please replace the paragraph starting on line 18, with the following amended paragraph:

Fig. 2 shows a mass spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3).

Page 4, please replace the paragraph starting on line 21, with the following amended paragraph:

Fig. 3 shows a zoom scan spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3).

Page 4, please replace the paragraph starting on line 24, with the following amended paragraph:

Fig. 4 shows the result of liquid chromatography in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4), in which the top graph is a chromatogram detected by a UV at 215 nm and the bottom graph is a base peak chromatogram.

Page 4, please replace the paragraph starting on line 29, with the following amended paragraph:

Fig. 5 shows a mass spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4).

Page 4, please replace the paragraph starting on line 32, with the following amended paragraph:

Fig. 6 shows a zoom scan spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4).

Page 4, please replace the paragraph starting on line 35, with the following amended paragraph:

Fig. 7 shows the result of liquid chromatography in the liquid chromatography (LC)-mass spectrometry (MS) of the mixture of the peptide fragments SLSLSP (SEQ ID NO: 3) and SLSLSP-NH_2 (SEQ ID NO: 4), in which the top graph is a chromatogram detected by a UV at 215 nm and the bottom graph is a base peak chromatogram.

Page 5, please replace the paragraph starting on line 8, with the following amended paragraph:

Fig. 10 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody (Main) followed by trypsin digestion; Fig. 10 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 10 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 10 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5).

Page 5, please replace the paragraph starting on line 26, with the following amended paragraph:

Fig. 14 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 1 followed by trypsin digestion; Fig. 14 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 14 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 14 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5).

Page 6, please replace the paragraph starting on line 20, with the following amended paragraph:

Fig. 21 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 2 followed by trypsin digestion; Fig. 21 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 21 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 21 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5).

Page 20, please replace the paragraph starting on line 26, with the following amended paragraph:

As the materials, the native humanized PM-1 antibody (sometimes referred to as Main), the subtypes 1 and 2 of said antibody, and, as the reference peptides, a peptide Ser-Leu-Ser-Leu-Ser-Pro (SLSLSP) (SEQ ID NO: 3) that is present at the C-terminal of the humanized PM-1 antibody and in which Gly at the C-terminal has been removed and a peptide SLSLSP-NH_2 (SEQ ID NO: 4) in which the C-terminal Pro has been amidated were used. The peptide SLSLSP (SEQ ID NO: 3) and the amidated peptide SLSLSP-NH_2 (SEQ ID NO: 4) were chemically synthesized. The humanized PM-1 antibody Main and the subtypes 1 and 2 of said antibody were obtained by subjecting the humanized PM-1 antibody obtained in Example 1 to a column chromatography and collecting and purifying it by the following method.

Page 22, please replace the paragraph starting on line 13, with the following amended paragraph:

Forty μl of each sample treated as above was subjected to the liquid chromatography-mass spectrometry (LC-MS/MS). For the reference peptide solutions, i.e. the SLSLSP (SEQ ID NO: 3) solution (SLSLSP (SEQ ID NO: 3) is dissolved in water to make 4 μM) and the SLSLSP-NH_2 (SEQ ID NO: 4) solution (SLSLSP-NH_2 (SEQ ID NO: 4) is dissolved in water to make 4 μM), 50 μl is subjected to the liquid chromatography-mass spectrometry.

Page 22, please replace the paragraph starting on line 33, with the following amended paragraph:

(1) Measurement of the reference peptide fragments

(a) Measurement of the peptide fragment SLSLSP (SEQ ID NO: 3)

Fig. 1 to Fig. 3 show the result of liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3). The top of Fig. 1 shows a chromatogram detected with a UV at 215 nm, and the bottom shows a chromatogram of a base peak chromatogram. Fig. 2 shows a mass spectrum, and Fig. 3 shows a zoom scan spectrum. The molecular weight (602.2) obtained was in close agreement with the theoretical value (602.3; monoisotopic molecular weight) (Fig. 2 and Fig. 3).

Page 23, please replace the paragraph starting on line 8, with the following amended paragraph:

(b) Measurement of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4)

Fig. 4 to Fig. 6 show the result of liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3). The top of Fig. 4 shows a chromatogram detected with a UV at 215 nm, and the bottom shows a chromatogram of a base peak chromatogram. Fig. 5 shows a mass spectrum, and Fig. 6 shows a zoom scan spectrum. The molecular weight (601.2) obtained was in close agreement with the theoretical value (601.3; monoisotopic molecular weight) (Fig. 5 and Fig. 6).

Page 23, please replace the paragraph starting on line 18, with the following amended paragraph:

(c) Measurement of the mixture of the peptide fragments SLSLSP (SEQ ID NO: 3) and SLSLSP-NH_2 (SEQ ID NO: 4)

Fig. 7 to Fig. 9 show the result of liquid chromatography (LC)-mass spectrometry (MS) of the mixture of the peptide fragment SLSLSP (SEQ ID NO: 3) and SLSLSP-NH_2 (SEQ ID NO: 4). The top of Fig. 7 shows a chromatogram detected with a UV at 215 nm, and the bottom shows a

chromatogram of a base peak chromatogram. Fig. 8 shows the mass spectrum of a peak at a retention time of 44 minutes in Fig. 7, and Fig. 9 shows the mass spectrum of a peak at a retention time of 51 minutes in Fig. 7. The both peptide fragments were completely separated under the condition of the above liquid chromatography.

Page 23, please replace the paragraph starting on line 35, with the following amended paragraph:

Fig. 10 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody (Main) followed by trypsin digestion. In order to investigate the structure of the C-terminal fragment of the H chain, the MS chromatogram of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3±0.5) is shown in Fig. 10 B, that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3±0.5) in Fig. 10 C, and that of SLSLSP (SEQ ID NO: 4) (selective monitoring at m/z 603.3±0.5) in Fig. 10 D. A peak corresponding to SLSLSPG (SEQ ID NO: 5) was detected at 49.7 minutes, but no peptide fragments having the molecular weight of SLSLSP-NH_2 (SEQ ID NO: 4) and SLSLSP (SEQ ID NO: 3) were found.

Page 24, please replace the paragraph starting on line 10, with the following amended paragraph:

Fig. 11 to Fig. 13 show the result of LC-MS/MS analysis of a peptide obtained by the reduction/carboxymethylation of the humanized PM-1 antibody (Main) followed by trypsin digestion. The top in Fig. 11 shows a chromatogram detected by a UV at 215 nm and the bottom shows a base peak chromatogram. Fig. 12 shows a mass spectrum of the peak at a retention time of 50 minutes in Fig. 11, and Fig. 13 shows a zoom scan spectrum of the same peak as in Fig. 11. From these results, the detected peak was shown to have the amino acid sequence SLSLSPG (SEQ ID NO: 5). Thus, it was demonstrated that both C-terminals of the H chain of the humanized PM-1 antibody (Main) have the -SLSLSPG (SEQ ID NO: 5) sequence.

Page 24, please replace the paragraph starting on line 25, with the following amended paragraph:

Fig. 14 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 1 followed by trypsin digestion. In order to investigate the structure of the C-terminal fragment of the H chain, Fig. 14 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5). Fig. 14 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 14 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5). In addition to a peak corresponding to SLSLSPG (SEQ ID NO: 5) at 47.7 minutes, a peak corresponding to SLSLSP-NH_2 (SEQ ID NO: 4) at 46.2 minutes was noted (though a peak with a molecular weight of 603.3 was noted at about 46 minutes in Fig. 14 D, it is not SLSLSP (SEQ ID NO: 3), based on the retention time).

Page 25, please replace the paragraph starting on line 22, with the following amended paragraph:

From these results, the detected peak was shown to have the amino acid sequences SLSLSPG (SEQ ID NO: 5) and SLSLSP-NH_2 (SEQ ID NO: 4). Thus, it was demonstrated that one of the H chain C-terminals of the humanized PM-1 antibody subtype 1 has the -SLSLSPG sequence (SEQ ID NO: 5), and the other has the -SLSLSPG-NH_2 sequence (SEQ ID NO: 6).

Page 25, please replace the paragraph starting on line 30, with the following amended paragraph:

Fig. 21 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 2 followed by trypsin digestion. In order to investigate the structure of the C-terminal fragment of the H chain, Fig. 21 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 21 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 21 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5). Though a peak

corresponding to SLSLSPG (SEQ ID NO: 5) was slightly detected, a peak corresponding to SLSLSP-NH_2 (SEQ ID NO: 4) was more strongly noted (though a peak with a molecular weight of 603.3 was noted at about 45 minutes in Fig. 21 D, it is not SLSLSP (SEQ ID NO: 3), based on the retention time).

Page 26, please replace the paragraph starting on line 7, with the following amended paragraph:

Fig. 22 to Fig. 24 show the result of LC-MS/MS analysis of a peptide obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 2 followed by trypsin digestion. In Fig. 22, the top is a chromatogram detected by a UV at 215 nm and the bottom is a base peak chromatogram. Fig. 23 shows a mass spectrum of the peak at a retention time of 45 minutes in Fig. 22, and Fig. 24 shows a zoom scan spectrum of the same peak as in Fig. 23. From these results, the detected peak was shown to have the amino acid sequence SLSLSP-NH_2 (SEQ ID NO: 4). Thus, it was demonstrated that both of the H chain C-terminals of the humanized PM-1 antibody subtype 2 have the -SLSLSPG-NH_2 sequence (SEQ ID NO: 6).

REMARKS

The specification was amended to include SEQ ID NOS. No new matter was added.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **350292003100**.

Dated: April 7, 2010

Respectfully submitted,

By _____
Jonathan Bockman
Registration No.: 45,640
MORRISON & FOERSTER LLP
1650 Tysons Blvd, Suite 400
McLean, Virginia 22102
(703) 760-7769

COPY OF DOCUMENTS SUBMITTED ON

DECEMBER 4, 2009,

IN RESPONSE TO THE

NOTIFICATION OF ABANDONMENT

PTO-1390 (Rev. 09-2007)
Approved for use through 02/28/2010. OMB 0651-0021
U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (if known, see 37 CFR 1.5)
350292003100	10/593,786

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/JP2005/006229	24 March 2005	24 March 2004

TITLE OF INVENTION
SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR

APPLICANT(S) FOR DO/EO/US
Katsuhiro KANO et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [ ] This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. [x] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. [ ] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [ ] The US has been elected (Article 31).
5. [ ] A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [ ] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [x] A preliminary amendment.
14. [ ] An Application Data Sheet under 37 CFR 1.76.
15. [ ] A substitute specification.
16. [ ] A power of attorney and/or change of address letter.
17. [x] A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821 – 1.825.
18. [ ] A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

PTO-1390 (Rev. 09-2007)
Approved for use through 02/28/2010. OMB 0651-0021
U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/593,786	PCT/JP2005/006229	350292003100

20. [x] Other items or information:
Petition to Withdraw the Holding of Abandonment (2 pages)
Copy of Notification of Abandonment (1 page)
Statement Under 37 CFR 1.825(a) and 1.825(b) (2 pages)
Paper Copy of Sequence Listing (4 pages)
Copy of Sequence Listing Validation Report (6 pages)
Copy of Image File Wrapper from PAIR (2 pages)

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. [ ] Basic national fee (37 CFR 1.492(a)) $310	$	
22. [ ] Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 All other situations $210	$	
23. [ ] Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... $100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... $410 All other situations $510	$	
TOTAL OF 21, 22 and 23 =	$ 0.00	
[ ] Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is **$260** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
- 100 =	/50 =		x $260.00	$

Surcharge of **$130** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).			$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x	x $50	0.00
Independent claims	- 3 =	0	x	x $210	0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+	+ $370	
				TOTAL OF ABOVE CALCULATIONS =	$
[ ] Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
				SUBTOTAL =	$
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					$
				TOTAL NATIONAL FEE =	$
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +					$
					$
				TOTAL FEES ENCLOSED =	$
				Amount to be refunded:	$
				Amount to be charged	$

PTO-1390 (Rev. 09-2007)
Approved for use through 02/28/2010. OMB 0651-0021
U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

a. [ ] A check in the amount of $ _____ to cover the above fees is enclosed.

b. [X] Please charge my Deposit Account No. 03-1952 in the amount of $ 00.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

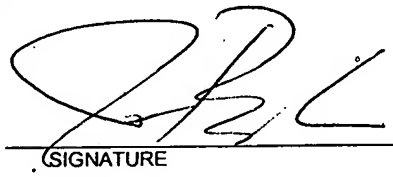
c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952 . A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR.** To protect your information, it is recommended paying fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:



SIGNATURE

Jonathan Bockman
NAME

CUSTOMER NUMBER: 25227

45,640
REGISTRATION NUMBER

DATE: December 4, 2009

Docket No.: 350292003100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Katsuhiro KANO et al.

Application No.: 10/593,786 Confirmation No.: 4027

Filed: March 24, 2005 Art Unit: Not Yet Assigned

For: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR Examiner: Not Yet Assigned

PETITION TO WITHDRAW THE HOLDING OF ABANDONMENT UNDER 37 CFR 1.181(a)

MS PCT
ATTN: Office of PCT Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants request withdrawal of abandonment for the above-referenced application. Applicants have received a Notification of Abandonment dated October 5, 2009. The Notice of Abandonment states that the application is abandoned because of Applicants' failure to timely file a proper reply to the notification of Missing Requirements mailed June 27, 2008.

Applicants, in fact, did respond to the notice on August 26, 2008, after which they received a a Notification of Defective Response, date March 20, 2009. Once again a response was filed on April 20, 2009. In reviewing PAIR, it was discovered that the Sequence Listing submitted had been reviewed on August 7, 2009, and was found once again to be defective by the reviewer, but a notice indicating that our computer readable form (CRF) was defective was never mailed to us.

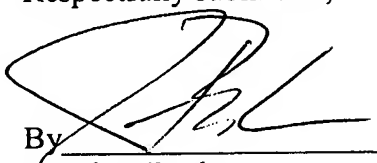
Therefore, we are attaching the following to this report:

1. Copy of Notification of Abandonment;
2. Statement Under 37 CFR 1.825(a) and 1.825(b);
3. Paper copy of the Sequence Listing;
4. Copy of Sequence Listing Validation Report;
5. Copy of Image File Wrapper from PAIR;
6. Computer disk containing the Sequence Listing in ASCII format;
7. Preliminary Amendment.

For the reasons stated herein, Applicants respectfully request that this Notice of Abandonment be promptly withdrawn.

Dated: December 4, 2009

Respectfully submitted,



By _____

Jonathan Bockman
Registration No.: 45,640
MORRISON & FOERSTER LLP
1650 Tysons Blvd, Suite 400
McLean, Virginia 22102
(703) 760-7769

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/593,786	Katsuhiro Kano	350292003100

25227
MORRISON & FOERSTER LLP
1650 TYSONS BOULEVARD
SUITE 400
MCLEAN, VA 22102

INTERNATIONAL APPLICATION NO.	
PCT/JP2005/006229	
I.A. FILING DATE	PRIORITY DATE
03/24/2005	03/24/2004

CONFIRMATION NO. 4027

371

ABANDONMENT/TERMINATION LETTER

OC000000038091701

Date Mailed: 10/05/2009

NOTIFICATION OF ABANDONMENT

The United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495) has made the following determination:

- Applicant has failed to respond to the notification of MISSING REQUIREMENTS (Form PCT/DO/EO/905), mailed 06/27/2008 within the time period set therein.

Therefore, the above identified application failed to meet the requirements of 35 U.S.C. 371 and 37 CFR 1.495,and is ABANDONED AS TO THE UNITED STATES OF AMERICA.

ANITA D JOHNSON

Telephone: (571) 272-0386

Docket No.: 350292003100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Katsuhiro KANO et al.

Application No.: 10/593,786 Confirmation No.: 4027

Filed: March 24, 2005 Art Unit: Not Yet Assigned

For: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR Examiner: Not Yet Assigned

STATEMENT UNDER 37 C.F.R. 1.825(a) and 1.825(b)

MS PCT
ATTN: Office of PCT Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned hereby states that the content of the attached paper copy of the substitute Sequence Listing and the computer readable copy of the substitute Sequence Listing submitted in accordance with 37 C.F.R. §§ 1.821-1.825, are identical. The submission of the substitute Sequence Listing does not include new matter.

The substitute Sequence Listing enclosed herewith has been amended to facilitate its administrative processing, and not for reasons related to patentability.

Applicants request consideration and entry of the Sequence Listing paper copy and computer readable copy. Pursuant to 37 C.F.R. 1.77, please enter the paper copy of the Sequence Listing after the Abstract.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and

authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **350292003100**.

Dated: December 4, 2009

Respectfully submitted,

By _____
Jonathan Bockman
Registration No.: 45,640
MORRISON & FOERSTER LLP
1650 Tysons Blvd, Suite 400
McLean, Virginia 22102
(703) 760-7769

SEQUENCE LISTING

<110> KANO, Katsuhiro
TERASHIMA, Isamu

<120> SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKIN-6 RECEPTOR

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His Ala Trp Ser Trp Val Arg Gln Pro Pro Gly Arg Gly Leu Glu Trp
        35                  40                  45
Ile Gly Tyr Ile Ser Tyr Ser Gly Ile Thr Thr Tyr Asn Pro Ser Leu
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Lys Ser Arg Val Thr Met Leu Arg Asp Thr Ser Lys Asn Gln Phe Ser
65                  70                  75                  80
Leu Arg Leu Ser Ser Val Thr Ala Ala Asp Thr Ala Val Tyr Tyr Cys
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Ala Arg Ser Leu Ala Arg Thr Thr Ala Met Asp Tyr Trp Gly Gln Gly
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Ser Leu Val Thr Val Ser Ser Ala Ser Thr Lys Gly Pro Ser Val Phe
        115                 120                 125
Pro Leu Ala Pro Ser Ser Lys Ser Thr Ser Gly Gly Thr Ala Ala Leu
    130                 135                 140
Gly Cys Leu Val Lys Asp Tyr Phe Pro Glu Pro Val Thr Val Ser Trp
145                 150                 155                 160
Asn Ser Gly Ala Leu Thr Ser Gly Val His Thr Phe Pro Ala Val Leu
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Thr His Thr Cys Pro Pro Cys Pro Ala Pro Glu Leu Leu Gly Gly Pro
225                 230                 235                 240
Ser Val Phe Leu Phe Pro Pro Lys Pro Lys Asp Thr Leu Met Ile Ser
                245                 250                 255
Arg Thr Pro Glu Val Thr Cys Val Val Val Asp Val Ser His Glu Asp
            260                 265                 270
Pro Glu Val Lys Phe Asn Trp Tyr Val Asp Gly Val Glu Val His Asn
        275                 280                 285
Ala Lys Thr Lys Pro Arg Glu Glu Gln Tyr Asn Ser Thr Tyr Arg Val
    290                 295                 300
Val Ser Val Leu Thr Val Leu His Gln Asp Trp Leu Asn Gly Lys Glu
305                 310                 315                 320
Tyr Lys Cys Lys Val Ser Asn Lys Ala Leu Pro Ala Pro Ile Glu Lys
                325                 330                 335
Thr Ile Ser Lys Ala Lys Gly Gln Pro Arg Glu Pro Gln Val Tyr Thr
            340                 345                 350
Leu Pro Pro Ser Arg Asp Glu Leu Thr Lys Asn Gln Val Ser Leu Thr
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Cys Leu Val Lys Gly Phe Tyr Pro Ser Asp Ile Ala Val Glu Trp Glu
    370                 375                 380
Ser Asn Gly Gln Pro Glu Asn Asn Tyr Lys Thr Thr Pro Pro Val Leu
385                 390                 395                 400
Asp Ser Asp Gly Ser Phe Phe Leu Tyr Ser Lys Leu Thr Val Asp Lys
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Ser Arg Trp Gln Gln Gly Asn Val Phe Ser Cys Ser Val Met His Glu
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Leu Asn Trp Tyr Gln Gln Lys Pro Gly Lys Ala Pro Lys Leu Leu Ile
        35                  40                  45
Tyr Tyr Thr Ser Arg Leu His Ser Gly Val Pro Ser Arg Phe Ser Gly
    50                  55                  60
Ser Gly Ser Gly Thr Asp Phe Thr Phe Thr Ile Ser Ser Leu Gln Pro
65                  70                  75                  80
Glu Asp Ile Ala Thr Tyr Tyr Cys Gln Gln Gly Asn Thr Leu Pro Tyr
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                85                  90                  95
Thr Phe Gly Gln Gly Thr Lys Val Glu Ile Lys Arg Thr Val Ala Ala
            100                 105                 110
Pro Ser Val Phe Ile Phe Pro Pro Ser Asp Glu Gln Leu Lys Ser Gly
        115                 120                 125
Thr Ala Ser Val Val Cys Leu Leu Asn Asn Phe Tyr Pro Arg Glu Ala
    130                 135                 140
Lys Val Gln Trp Lys Val Asp Asn Ala Leu Gln Ser Gly Asn Ser Gln
145                 150                 155                 160
Glu Ser Val Thr Glu Gln Asp Ser Lys Asp Ser Thr Tyr Ser Leu Ser
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Ser Thr Leu Thr Leu Ser Lys Ala Asp Tyr Glu Lys His Lys Val Tyr
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Sequence Listing could not be accepted due to errors.

See attached Validation Report.

If you need help call the Patent Electronic Business Center at (866) 217-9197 (toll free).

Reviewer: markspencer

Timestamp: [year=2009; month=8; day=7; hr=14; min=22; sec=40; ms=727;]

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Reviewer Comments:

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E201 Mandatory field data missing in <221> in SEQ ID (1)

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Please provide a space between the numeric identifiers in these sequences and their responses. Using SEQ ID # 1 as an example your sequences should look like the following.

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Application No: 10593786 Version No: 2.0

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TERASHIMA, Isamu

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Docket No.: 350292003100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Katsuhiro KANO et al.

Application No.: 10/593,786 Confirmation No.: 4027

Filed: March 24, 2005 Art Unit: Not Yet Assigned

For: SUBTYPES OF HUMANIZED ANTIBODY AGAINST INTERLEUKEN-6 RECEPTOR Examiner: Not Yet Assigned

FIRST PRELIMINARY AMENDMENT

MS PCT
ATTN: Office of PCT Legal Administration
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Prior to examination on the merits, Applicants respectfully request entry on this Preliminary Amendment for the above-captioned patent application.

Amendments to the Specification begin on page 8.

Remarks begin on page 9.

AMENDMENTS

In the Specification:

Page 4, please replace the paragraph starting on line 13, with the following amended paragraph:

Fig. 1 shows the result of liquid chromatography in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3), in which the top graph is a chromatogram detected by a UV at 215 nm and the bottom graph is a base peak chromatogram.

Page 4, please replace the paragraph starting on line 18, with the following amended paragraph:

Fig. 2 shows a mass spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3).

Page 4, please replace the paragraph starting on line 21, with the following amended paragraph:

Fig. 3 shows a zoom scan spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3).

Page 4, please replace the paragraph starting on line 24, with the following amended paragraph:

Fig. 4 shows the result of liquid chromatography in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4), in which the top graph is a chromatogram detected by a UV at 215 nm and the bottom graph is a base peak chromatogram.

Page 4, please replace the paragraph starting on line 29, with the following amended paragraph:

Fig. 5 shows a mass spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4).

Page 4, please replace the paragraph starting on line 32, with the following amended paragraph:

Fig. 6 shows a zoom scan spectrum in the liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4).

Page 4, please replace the paragraph starting on line 35, with the following amended paragraph:

Fig. 7 shows the result of liquid chromatography in the liquid chromatography (LC)-mass spectrometry (MS) of the mixture of the peptide fragments SLSLSP (SEQ ID NO: 3) and SLSLSP-NH_2 (SEQ ID NO: 4), in which the top graph is a chromatogram detected by a UV at 215 nm and the bottom graph is a base peak chromatogram.

Page 5, please replace the paragraph starting on line 8, with the following amended paragraph:

Fig. 10 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody (Main) followed by trypsin digestion; Fig. 10 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 10 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 10 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5).

Page 5, please replace the paragraph starting on line 26, with the following amended paragraph:

Fig. 14 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 1 followed by trypsin digestion; Fig. 14 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 14 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 14 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5).

Page 6, please replace the paragraph starting on line 20, with the following amended paragraph:

Fig. 21 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 2 followed by trypsin digestion; Fig. 21 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 21 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 21 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5).

Page 20, please replace the paragraph starting on line 26, with the following amended paragraph:

As the materials, the native humanized PM-1 antibody (sometimes referred to as Main), the subtypes 1 and 2 of said antibody, and, as the reference peptides, a peptide Ser-Leu-Ser-Leu-Ser-Pro (SLSLSP) (SEQ ID NO: 3) that is present at the C-terminal of the humanized PM-1 antibody and in which Gly at the C-terminal has been removed and a peptide SLSLSP-NH_2 (SEQ ID NO: 4) in which the C-terminal Pro has been amidated were used. The peptide SLSLSP (SEQ ID NO: 3) and the amidated peptide SLSLSP-NH_2 (SEQ ID NO: 4) were chemically synthesized. The humanized PM-1 antibody Main and the subtypes 1 and 2 of said antibody were obtained by subjecting the humanized PM-1 antibody obtained in Example 1 to a column chromatography and collecting and purifying it by the following method.

Page 22, please replace the paragraph starting on line 13, with the following amended paragraph:

Forty μl of each sample treated as above was subjected to the liquid chromatography-mass spectrometry (LC-MS/MS). For the reference peptide solutions, i.e. the SLSLSP (SEQ ID NO: 3) solution (SLSLSP (SEQ ID NO: 3) is dissolved in water to make 4 μM) and the SLSLSP-NH_2 (SEQ ID NO: 4) solution (SLSLSP-NH_2 (SEQ ID NO: 4) is dissolved in water to make 4 μM), 50 μl is subjected to the liquid chromatography-mass spectrometry.

Page 22, please replace the paragraph starting on line 33, with the following amended paragraph:

(1) Measurement of the reference peptide fragments

(a) Measurement of the peptide fragment SLSLSP (SEQ ID NO: 3)

Fig. 1 to Fig. 3 show the result of liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3). The top of Fig. 1 shows a chromatogram detected with a UV at 215 nm, and the bottom shows a chromatogram of a base peak chromatogram. Fig. 2 shows a mass spectrum, and Fig. 3 shows a zoom scan spectrum. The molecular weight (602.2) obtained was in close agreement with the theoretical value (602.3; monoisotopic molecular weight) (Fig. 2 and Fig. 3).

Page 23, please replace the paragraph starting on line 8, with the following amended paragraph:

(b) Measurement of the peptide fragment SLSLSP-NH_2 (SEQ ID NO: 4)

Fig. 4 to Fig. 6 show the result of liquid chromatography (LC)-mass spectrometry (MS) of the peptide fragment SLSLSP (SEQ ID NO: 3). The top of Fig. 4 shows a chromatogram detected with a UV at 215 nm, and the bottom shows a chromatogram of a base peak chromatogram. Fig. 5 shows a mass spectrum, and Fig. 6 shows a zoom scan spectrum. The molecular weight (601.2) obtained was in close agreement with the theoretical value (601.3; monoisotopic molecular weight) (Fig. 5 and Fig. 6).

Page 23, please replace the paragraph starting on line 18, with the following amended paragraph:

(c) Measurement of the mixture of the peptide fragments SLSLSP (SEQ ID NO: 3) and SLSLSP-NH_2 (SEQ ID NO: 4)

Fig. 7 to Fig. 9 show the result of liquid chromatography (LC)-mass spectrometry (MS) of the mixture of the peptide fragment SLSLSP (SEQ ID NO: 3) and SLSLSP-NH_2 (SEQ ID NO: 4). The top of Fig. 7 shows a chromatogram detected with a UV at 215 nm, and the bottom shows a

chromatogram of a base peak chromatogram. Fig. 8 shows the mass spectrum of a peak at a retention time of 44 minutes in Fig. 7, and Fig. 9 shows the mass spectrum of a peak at a retention time of 51 minutes in Fig. 7. The both peptide fragments were completely separated under the condition of the above liquid chromatography.

Page 23, please replace the paragraph starting on line 35, with the following amended paragraph:

Fig. 10 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody (Main) followed by trypsin digestion. In order to investigate the structure of the C-terminal fragment of the H chain, the MS chromatogram of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3±0.5) is shown in Fig. 10 B, that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3±0.5) in Fig. 10 C, and that of SLSLSP (SEQ ID NO: 4) (selective monitoring at m/z 603.3±0.5) in Fig. 10 D. A peak corresponding to SLSLSPG (SEQ ID NO: 5) was detected at 49.7 minutes, but no peptide fragments having the molecular weight of SLSLSP-NH_2 (SEQ ID NO: 4) and SLSLSP (SEQ ID NO: 3) were found.

Page 24, please replace the paragraph starting on line 10, with the following amended paragraph:

Fig. 11 to Fig. 13 show the result of LC-MS/MS analysis of a peptide obtained by the reduction/carboxymethylation of the humanized PM-1 antibody (Main) followed by trypsin digestion. The top in Fig. 11 shows a chromatogram detected by a UV at 215 nm and the bottom shows a base peak chromatogram. Fig. 12 shows a mass spectrum of the peak at a retention time of 50 minutes in Fig. 11, and Fig. 13 shows a zoom scan spectrum of the same peak as in Fig. 11. From these results, the detected peak was shown to have the amino acid sequence SLSLSPG (SEQ ID NO: 5). Thus, it was demonstrated that both C-terminals of the H chain of the humanized PM-1 antibody (Main) have the -SLSLSPG (SEQ ID NO: 5) sequence.

Page 24, please replace the paragraph starting on line 25, with the following amended paragraph:

Fig. 14 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 1 followed by trypsin digestion. In order to investigate the structure of the C-terminal fragment of the H chain, Fig. 14 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5). Fig. 14 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 14 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5). In addition to a peak corresponding to SLSLSPG (SEQ ID NO: 5) at 47.7 minutes, a peak corresponding to SLSLSP-NH_2 (SEQ ID NO: 4) at 46.2 minutes was noted (though a peak with a molecular weight of 603.3 was noted at about 46 minutes in Fig. 14 D, it is not SLSLSP (SEQ ID NO: 3), based on the retention time).

Page 25, please replace the paragraph starting on line 22, with the following amended paragraph:

From these results, the detected peak was shown to have the amino acid sequences SLSLSPG (SEQ ID NO: 5) and SLSLSP-NH_2 (SEQ ID NO: 4). Thus, it was demonstrated that one of the H chain C-terminals of the humanized PM-1 antibody subtype 1 has the -SLSLSPG sequence (SEQ ID NO: 5), and the other has the -SLSLSPG-NH_2 sequence (SEQ ID NO: 6).

Page 25, please replace the paragraph starting on line 30, with the following amended paragraph:

Fig. 21 A shows a peptide map of peptides obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 2 followed by trypsin digestion. In order to investigate the structure of the C-terminal fragment of the H chain, Fig. 21 B shows the MS chromatogram of molecular weight of SLSLSPG (SEQ ID NO: 5) (selective monitoring at m/z 660.3 ± 0.5), Fig. 21 C shows that of SLSLSP-NH_2 (SEQ ID NO: 4) (selective monitoring at m/z 602.3 ± 0.5), and Fig. 21 D shows that of SLSLSP (SEQ ID NO: 3) (selective monitoring at m/z 603.3 ± 0.5). Though a peak

corresponding to SLSLSPG (SEQ ID NO: 5) was slightly detected, a peak corresponding to SLSLSP-NH_2 (SEQ ID NO: 4) was more strongly noted (though a peak with a molecular weight of 603.3 was noted at about 45 minutes in Fig. 21 D, it is not SLSLSP (SEQ ID NO: 3), based on the retention time).

Page 26, please replace the paragraph starting on line 7, with the following amended paragraph:

Fig. 22 to Fig. 24 show the result of LC-MS/MS analysis of a peptide obtained by the reduction/carboxymethylation of the humanized PM-1 antibody subtype 2 followed by trypsin digestion. In Fig. 22, the top is a chromatogram detected by a UV at 215 nm and the bottom is a base peak chromatogram. Fig. 23 shows a mass spectrum of the peak at a retention time of 45 minutes in Fig. 22, and Fig. 24 shows a zoom scan spectrum of the same peak as in Fig. 23. From these results, the detected peak was shown to have the amino acid sequence SLSLSP-NH_2 (SEQ ID NO: 4). Thus, it was demonstrated that both of the H chain C-terminals of the humanized PM-1 antibody subtype 2 have the -SLSLSPG-NH_2 sequence (SEQ ID NO: 6).

REMARKS

The specification was amended to include SEQ ID NOS. No new matter was added.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **350292003100**.

Dated: December 4, 2009

Respectfully submitted,

By _____

Jonathan Bockman
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McLean, Virginia 22102
(703) 760-7769